

§ 84.34

is manufactured according to the drawings and specifications upon which the certificate of approval is based.

(g) Each respirator, respirator component, and respirator container shall, as required by the Institute to assure quality control and proper use of the respirator, be labeled distinctly to show the name of the applicant, and the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or approximate date of manufacture.

§ 84.34 Revocation of certificates of approval.

The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval.

§ 84.35 Changes or modifications of approved respirators; issuance of modification of certificate of approval.

(a) Each applicant may, if he desires to change any feature of an approved respirator, request a modification of the original certificate of approval issued by the Institute for such respirator by filing an application for such modification in accordance with the provisions of this section.

(b) Applications shall be submitted as for an original certificate of approval, with a request for a modification of the existing certificate to cover any proposed change.

(c) The application shall be accompanied by appropriate drawings and specifications, and by a proposed quality control plan which meets the requirements of subpart E of this part.

(d) The application for modification, together with the accompanying material, shall be examined by the Institute to determine whether testing will be required.

(e) The Institute shall inform the applicant of the fee required for any additional testing and the applicant will be

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charged for the actual cost of any examination, inspection, or test required, and such fees shall be submitted in accordance with the provisions of subpart C of this part.

(f) If the proposed change or modification meets the requirements of this part, a formal certificate of modification will be issued, accompanied, where necessary, by a list of new and revised drawings and specifications covering the change(s) and reproductions of revised approval labels.

(The information collections contained in this section are approved under OMB control number 0920–0109)

§ 84.36 Delivery of changed or modified approved respirator.

An approved respirator for which a formal certificate of modification has been issued shall be delivered, with proper markings and containers, by the applicant to the Certification and Quality Assurance Branch, as soon as it is commercially produced.

Subpart E—Quality Control

§ 84.40 Quality control plans; filing requirements.

As a part of each application for approval or modification of approval submitted pursuant to this part, each applicant shall file with the Institute a proposed quality control plan which shall be designed to assure the quality of respiratory protection provided by the respirator for which approval is sought.

§ 84.41 Quality control plans; contents.

(a) Each quality control plan shall contain provisions for the management of quality, including:

(1) Requirements for the production of quality data and the use of quality control records;

(2) Control of engineering drawings, documentations, and changes;

(3) Control and calibration of measuring and test equipment;

(4) Control of purchased material to include incoming inspection;

(5) Lot identification, control of processes, manufacturing, fabrication, and assembly work conducted in the applicant's plant;